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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,717	01/28/2002	Douglas William Hamilton	7250-11	8819

7590

04/20/2005

Thomas Q Henry
Woodard Emhardt Naughton Moriarty & McNett
Bank One Tower
111 Monument Circle Suite 3700
Indianapolis, IN 46204

EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,717

Applicant(s)

HAMILTON ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-19 and 21-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14, 16-19 and 21-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Applicants' amendments filed on March 21, 2005 have been received and entered. Claims 1, 16, 19 and 21-23 have been amended. Claims 15, 20 and 24-28 have been canceled. No claims have been added. Claims 19 and 21-23, formerly withdrawn product claims, have been amended to depend from claim 1. Accordingly, claims 1-14, 16-19 and 21-23 are pending and are examined on the merits herewith.

The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

In view of Applicants' amendments and explanations, the rejection of claims 13 and 16 under 35 USC § 112, second paragraph, is withdrawn.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "various levels and gradients types of growth factor" that are entrapped in the cell culture fiber substrate used in the claimed method. Such claim language is confusing, as Applicants' intended meaning cannot be determined. Applicants may wish to amend this claim to state clearly what is entrapped in the fibers.

Claim Rejections - 35 USC § 102

In view of Applicants' amendments to the claims, the rejections under 35 USC § 102(b) are withdrawn.

Claim Rejections - 35 USC § 103

Claims 1-14 and 16-18 are again rejected, and claims 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al. (WO 95/22305) in view of The University of Strathclyde (EP 419234, hereinafter referred to as "Strathclyde"), and Hansbrough et al. (US 5,460,939). The rejection of these claims prior to the latest amendments as being unpatentable over Curtis et al. in view of Strathclyde was discussed in a previous Office action.

All of Applicants' arguments have been considered but are not persuasive of error. Applicants have amended their claims to recite that the fibers in the claimed cell culture method are made of at least one biodegradable material from a particular group of materials. Applicants assert that their invention is not obvious because Curtis et al. and Strathclyde do not teach these biodegradable materials.

In reply, Curtis et al. do teach that their cell culture fibers may be made of biodegradable materials and that a wide variety of acceptable biodegradable materials are known. Curtis et al. provide a number of examples of such materials. Some of these materials are synthetic polymers and others are natural polymers. Examples of natural polymers are collagen and polysaccharides. Applicants' claimed materials include the natural polysaccharides alginate, chitosan and hyaluronic acid. Hansbrough

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et al. disclose a method of culturing eukaryotic cells on fiber frameworks that are made of biodegradable materials such as chitin, chitosan, chitosan derivatives, hyaluronic acid or other polysaccharides. The fiber frameworks may also be made of combinations of these polymers, such as chitin/chitosan and chitosan/N.O. carboxymethylchitosan (see col. 7, line 21, to col. 8, line 8). It would have been obvious to one of ordinary skill in the art at the time that the invention was made to make the cell culture fibers of a biodegradable material such as chitin, chitosan, chitosan derivatives, hyaluronic acid or combinations thereof, because Hansbrough et al. teach that these materials are highly biocompatible and better substrates for cell attachment than non-biodegradable materials (see col. 7, lines 8-20). Chitosan derivative fibers have greater water absorbancy than alginate fibers (see col. 8, lines 2-3). Chitin/chitosan frameworks have the properties of promoting hemostasis, cell attachment, wound healing, reducing scarring and reduced microbial growth (see col. 7, lines 33-42).

With respect to claim 23, which recites that the fiber substrate contains a growth factor, Hansbrough et al. disclose a fiber substrate containing fibroblasts, which produce various growth factors such as fibroblast growth factor, platelet-derived growth factor and insulin-like growth factor. Thus, the fiber substrates of Hansbrough et al. contain various growth factors that diffuse through the substrate (see col. 5, line 56, to col. 6, line 12, Example 6 in cols. 12-16, and Fig. 1). The amount and location of growth factors in the substrate may be regulated by the number of fibroblasts seeded, the placement of fibroblasts and the amount of time that the fibroblasts grow before the fiber substrate is implanted. It would have been obvious to one of ordinary skill in the art at

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the time that the invention was made to add growth factors to a fiber substrate for cell culture, because Hansbrough et al. teach that the presence of growth factors improves cell attachment and results in long-term survival of the implant (see col. 5, lines 56-60). Therefore, a holding of obviousness is again required.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

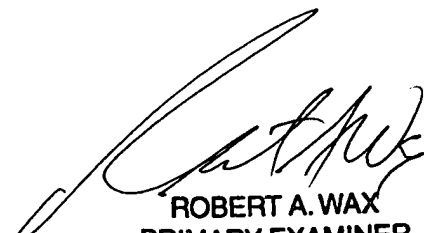
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

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2005-04-14



ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653